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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708,870	11/08/2000	Sean Farmer	19374-509 (GND-09)	2981

7590 05/03/2002

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EXAMINER

AFREMOVA, VERA

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 05/03/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/708,870	Applicant(s) Farmer	
	Examiner Vera Afremova	Art Unit 1651	
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>			
Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. <ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). 			
Status <p>1) <input type="checkbox"/> Responsive to communication(s) filed on _____.</p> <p>2a) <input type="checkbox"/> This action is FINAL. 2b) <input checked="" type="checkbox"/> This action is non-final.</p> <p>3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11; 453 O.G. 213.</p>			
Disposition of Claims <p>4) <input checked="" type="checkbox"/> Claim(s) <u>1-35</u> is/are pending in the application.</p> <p>4a) Of the above, claim(s) <u>1-24, 31, and 32</u> is/are withdrawn from consideration.</p> <p>5) <input type="checkbox"/> Claim(s) _____ is/are allowed.</p> <p>6) <input checked="" type="checkbox"/> Claim(s) <u>25-30 and 33-35</u> is/are rejected.</p> <p>7) <input type="checkbox"/> Claim(s) _____ is/are objected to.</p> <p>8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.</p>			
Application Papers <p>9) <input type="checkbox"/> The specification is objected to by the Examiner.</p> <p>10) <input type="checkbox"/> The drawing(s) filed on _____ is/are objected to by the Examiner.</p> <p>11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a)<input type="checkbox"/> approved b)<input type="checkbox"/> disapproved.</p> <p>12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p>			
Priority under 35 U.S.C. § 119 <p>13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).</p> <p>a)<input type="checkbox"/> All b)<input type="checkbox"/> Some* c)<input type="checkbox"/> None of:</p> <ol style="list-style-type: none"> 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). 			
<p>*See the attached detailed Office action for a list of the certified copies not received.</p> <p>14) <input checked="" type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).</p>			
Attachment(s) <p>15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>6, 8</u></p> <p>18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____</p> <p>19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>20) <input checked="" type="checkbox"/> Other: <i>Notice to comply for publication with SEQ disclosure</i></p>			

Art Unit: 1651

DETAILED ACTION

Applicant's election of Group III (claims 25-30 and 33-35) invention, drawn to a method for inhibiting pathogenic infection with composition comprising bacteria belonging to the genus of *Bacillus*, in the Paper No. 10 filed 3/20/2002 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-24, 31 and 32 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected, there being no allowable generic or linking claim.

Claims 25-30 and 33-35 are under examination in the instant office action.

Drawings

This application has been filed with informal drawings but only figures 1-5 and 9-11 are acceptable for examination purposes. Formal drawings will be required when the application is allowed.

The informal drawings 6-8 are not of sufficient quality to permit examination due to non-compliance with the requirements of 37 CFR 1.821 through 1.825 as related to nucleotide and/or amino acid sequences for the reason(s) set forth on the attached Notice to Comply With Requirements for Patent Applications Containing Nucleotide Sequence And/Or Amino Acid. Accordingly, new drawings are required in reply to this Office action.

Applicant is given a two month time period to submit new drawings in compliance with 37 CFR 1.81. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). Failure to timely submit new drawings will result in abandonment the application.

Art Unit: 1651

Specification

The disclosure is objected to because of the following informalities:

1. This application contains sequence disclosures (see figures 6, 7 and 8) that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice to Comply With Requirements for Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant is given one month extendable period within which to comply with the sequence rules, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in abandonment of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Applicant is requested to return a copy of the attached Notice to Comply with the response.

2. The specification contains blank spaces or some errors in the disclosure of bacterial strain accession numbers (see page 6, lines 22 and 26; page 7, lines 1-25).

Appropriate correction is required.

Art Unit: 1651

Claim Rejections - 35 USC § 112

Claims 25-30 and 33-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 is indefinite because it is depending on non-elected claim and, thus, compositions which is intended is uncertain as claimed.

Claims 25-28 are indefinite as related to “infected site” because it is uncertain whether the claimed method is an *in vivo* or an *in vitro* administration. In the instant office action the claimed method is interpreted as an in vivo application of a composition comprising bacteria belonging to the genus of *Bacillus*. Further, it is not particularly certain as claimed whether “an infected site” is infected with “a pathogenic bacterial infection” or with else such as fungal or viral infection, for example.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 25-30 and 33-35 are rejected under 35 U.S.C. 102(b) as being by US 5,968, 569 [A] or WO 98/54982 [N].

Art Unit: 1651

Claims are directed to a method of inhibiting pathogenic bacterial infection comprising contacting an infected site by administration of a composition comprising bacteria belonging to the genus of *Bacillus* or to the species of *Bacillus coagulans*. Some claims are further drawn to administration of the composition comprising either bacterial cells or bacterial spores and providing from 10^2 to 10^{14} viable cells or spores per day. Some claims are further drawn to administering bacterial composition to a gastrointestinal tract or to a mucous membrane or to various mode of administration of the bacterial composition.

US 5,968, 569 [A] teaches a method of inhibiting pathogenic bacterial infection such as *Clostridium perfringens* (col. 6 at line 59 or col. 9 at line 33) comprising contacting an infected site of mucous membrane by oral administration of a composition comprising bacteria belonging to the species of *Bacillus coagulans* (see examples 1 and 5). The cited patent is directed to treatment of gastrointestinal infection with probiotic bacterial composition or treatment of a mucous membrane of gastrointestinal tract. The cited patent also teaches that the bacterial composition contain from 10^4 to 10^{10} viable cells or spores (see col. 6, lines 9-12 and col. 7, line 49 and col.10, line 56) and that patients under treatment had unlimited access to the bacterial composition (col. 9, line 28).

The cited patent is considered to anticipate the claimed invention because the cited method teaches identical active step of oral administration of identical composition with bacteria belonging to the species of *Bacillus coagulans*. Further, it is reasonably expected that the patients under treatment have been administered identical amounts of bacterial composition daily as claimed particularly in view that the cited composition comprise substantially identical, if not

Art Unit: 1651

similar, amounts of cells or spores per g of the composition intended to be administered, patients had unlimited access to bacterial compositions and the pathogenic bacterial infection has been successfully inhibited as the result of practicing the cited method of administration as it is intended by the present method. Thus, the invention as claimed is anticipated by the cited patent.

WO 98/54982 [N] discloses a method of inhibiting pathogenic bacterial infection comprising contacting an infected site by administration of a composition comprising bacteria belonging to the genus of *Bacillus* or to the species of *Bacillus coagulans* and providing from 10^3 to 10^{12} viable cells or spores per day orally or anally to the mucous membrane (abstract; page 23, line 3, line 13; page 24, line 1; examples 8-9). The cited reference anticipates the invention as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25-29 and 33-35 are- rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,968, 569 [A] or WO 98/54982 [N] taken with Yanagida et al. [V] and Bergey' Manual [W].

The claims as explained above. The bacterial composition is intended to comprise bacteria belonging to the genus of *Bacillus* or to the species of *Bacillus coagulans* which capable to produce lactic acid and to grow at pH 2-5 and temperature 20-44°C.

Art Unit: 1651

The cited references are relied for the disclosure of a method of inhibiting pathogenic bacterial infection by administration of a composition comprising bacteria belonging to the genus of *Bacillus* or to the species of *Bacillus coagulans*.

Further, the cited references are relied upon to demonstrate that representatives of the genus of *Bacillus* or of the species of *Bacillus coagulans* are capable to produce lactic acid, to grow at temperature 20-44 °C (see Yanagida et al. [V] at table 1, pages 40-41) and to grow at pH 5 (see Bergey' Manual at page 1128, table 13.6).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to practice a method of administration of a bacterial composition with *Bacillus coagulans* with a reasonable expectation of success in inhibiting pathogenic bacteria because similar, if not identical, cultures have been known, taught and/or suggested in the prior art.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

Art Unit: 1651

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova,

Art Unit 1651

May 2, 2002.

Irene Mazy
IRENE MAZY
PRIMARY EXAMINER

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing."

5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

7. Other: _____

Applicant Must Provide:

An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

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